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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,435	01/18/2002	Gideon Bollag	ONYX1028/1028div/Formal D	7344

7590 12/24/2002

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[REDACTED] EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 10/054,435	Applicant(s) Bollag et al.
Examiner William Sandals	Art Unit 1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Jan 18, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-6, 30, 31, 36, 37, 44-53, and 56-67 <sup>And 36-67</sup> is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-6, 30, 31, 36, 37, 44-53, and 56-67 <sup>And 36-67</sup> are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 30 and 31, drawn to a RAC-GEF polypeptide, classified in class 530, subclass 350.
  - II. Claims 36, 37, 44 and 45, drawn to a method of modulating activity of GTPase with a GEF, classified in class 435, subclass 4.
  - III. Claims 38 and 39, drawn to a method of expression of a nucleic acid, classified in class 435, subclass 455.
  - IV. Claims 40-43, drawn to a method of isolating a compound which binds RAC polypeptide, classified in class 436, subclass 501.
  - V. Claims 46-48 and 50-52, drawn to a method of testing for an agent which modulates activity of a GEF, classified in class 436, subclass 8.
  - VI. Claims 49, 53 and 65, drawn to an agent which modulates the activity of GEF, classified in class 514, subclass 2.
  - VII. Claims 54-55, drawn to an antibody specific for a RAC-GEF polypeptide, classified in class 530, subclass 387.1.
  - VIII. Claims 56-59, drawn to a method of increasing GEF activity with a GTPase, classified in class 435, subclass 15.

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IX. Claims 60-64, drawn to a method of assaying for a compound to treat a disease, classified in class 424, subclass 9.2.

X. Claims 66-67, drawn to ligands that bind to Src homology III domains on RAC-GEF, classified in class 514, subclass 1.

2. The inventions are distinct, each from the other because of the following reasons:
  3. The RAC-GEF protein of Group I, the agent of Group VI, the antibody of Group VII and the ligand of Group X are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The RAC-GEF protein of Group I is not required to produce the agent which modulates the activity of GEF of Group VI, the agent of Group VI is not required to produce the antibody of Group VII, and the agent of Group VI and the antibody of Group VII are not required to produce the ligand of Group X. Therefore, the inventions of each of the Groups are capable of supporting separate patents.
  4. Inventions of Groups II-V and VIII-IX are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-V and VIII-IX comprise steps which are not required for or present in the methods of the other groups: Modulation of activity of a GTPase of (Group II), expression of a nucleic acid (Group III), isolating a compound which binds to a RAC polypeptide (Group IV), Testing for an agent which modulates the activity of a GEF (Group V), increasing the activity of a GTPase (Group VIII) and assaying for a compound to treat disease (Group IX). The end result of the methods are different and thus the operation, function and effects of these different methods are different and

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distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

5. Inventions of Group I and II-V & VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Rac GEF polypeptide is used in the three distinct and different methods of each of Groups II, V & IX.

6. Inventions of Group VI and II-V & VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent of Group VI is used in the two distinct and different methods of Groups IV & V.

7. Inventions of Group VII and II-V & VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the methods of Groups II-V & VIII-IX do not require the antibody and making the antibody does not require the methods of Groups II-V & VIII-IX.

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8. Inventions of Group X and Groups II-V & VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the making of the ligand of Group X does not require the methods of Groups II-V & VIII-IX and the methods of Groups II-V & VIII-IX do not require the ligand of Group X.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Conclusion*

12. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service at telephone number is (703) 308-0198.

William Sandals, Ph.D.  
Examiner  
December 21, 2002

  
TERRY MCKELVEY  
PRIMARY EXAMINER